

**Dear ecopa messenger subscriber,**

The kick-off-Meeting for *ecopa's* new EU-project START-UP was held in Leverkusen (Germany) and the first of 3 expert meetings took place in Madrid (Spain) in April and May 2008, respectively. The second was held in Basle in September, the third during the 3rd eSI event, currently ongoing in Spain. START-UP is a support action in the 7th Framework Programme-project realized as a close collaboration between NCPs.

The latest *ecopa* Board Meeting took place near Stockholm on September 25, 2008 and the members agreed on further planning and dates (please be advised that some dates have been adapted due to time updates and also locations might have changed).

*ecopa* Board Meeting Minutes to follow soon.

Next Board Meetings will be held together with the START-UP workshops. The dates and places are as follows:

- February 25, 2009 in Rome, Italy
- October 1, 2009 in Budapest, Hungary

In Madrid, the expert meeting of START-UP (organised as a closed session) was followed on the second day by a Spanish Platform-meeting (open to the public), organized by Peter Maier, the 3 R Swiss Platform and Interpharma.

The second expert meeting for the 7th FP-project START-UP, "3Rs and Animal Disease Models in Pharmaceutical Research and Development", has taken place on October 5 in Basle/CH on invitation by Peter Maier, the 3 R Swiss Platform and Interpharma.

Update of actual time schedule of all events for *ecopa* incl. START-UP:

<http://www.ecopa.eu/content/events.php>



[Minutes START-UP Kick-Off Meeting \(28 kb\)](#)



[START-UP Kick-Off- and Expert-Meeting presentations](#)



[START-UP 1st Expert-Meeting, Madrid, photographs](#)



[START-UP 2nd Expert-Meeting, Basle, photographs](#)

The currently ongoing eSI (*ecopa* Science Initiative)-Workshop in Alicante/Spain addresses: "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". Scheduled date is October 16-19, 2008 and is attended by senior scientists and young researcher of 14 European Nations. The European Partnership for Alternative Approaches to Animal Testing, EPAA, is participating in this important research event. The final program is shown on the *ecopa*-website.

**The next *ecopa* Annual Workshop will take place on November 29 and 30, 2008 in Brussels including the Annual Members Meeting. The topic is: "Cosmetics Directive, REACH legislation and novel Directive 86/609: 2009-2013 – Factual Status?". PLEASE REGISTER NOW!!!**



[Draft programme \(144 kb\)](#)



[Registration form: please register urgently! Deadline: November 10, 2008 \(36 kb\)](#)

Bernward Garthoff

Treasurer *ecopa* on behalf of the *ecopa* Management Board

P.S.: Any proposal or recommendation regarding style, content or distribution of the newsletter is highly welcome and appreciated ([bgarthoff@t-online.de](mailto:bgarthoff@t-online.de)). If you know other people or institutions interested, have them visit our website and [subscribe to this newsletter](#).

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## I.1. General News

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### I.1.1. Recent News on REACH

First REACH list of dangerous chemicals agreed:



<http://www.euractiv.com/en/environment/reach-list-dangerous-chemicals-agreed/article-176244>

The European Chemicals Agency (ECHA) has agreed on the first group of 15 "very high concern" chemicals to undergo special health and safety scrutiny under the bloc's chemical regulation REACH.

These are "only the first substances of very high concern identified through the formal process," stressed ECHA Executive Director Geert Dancet, adding that new proposals were being prepared and that the candidate list would be updated.

German Government has implemented a website on REACH, called REACH helpdesk with information, frequently asked questions and the documentations of the Europe-wide meetings and conferences on REACH. The site is in German only.



[http://www.reach-helpdesk.de/de/Startseite.html?\\_nnn=true](http://www.reach-helpdesk.de/de/Startseite.html?_nnn=true)

Most of the facts and the implementation aspects of REACH are found in the 60-page-report "Impact of REACH", first edition of a new series of *ecopa*-publications (electronic version). A print-version is available on request. Copies on CD also available, contact the *ecopa* secretariat.



[Impact of REACH \(804 kb\)](#)



## ECHA (European Chemical Agency)

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### European Chemicals Agency is operational

European Chemicals Agency (ECHA) has taken up duties. With June 1, 2008, the Agency launched the REACH-IT portal and started to accept pre-registrations and other data submissions from industry.

More information here: <http://echa.europa.eu/doc/press/>

Access to REACH-IT portal: [http://echa.europa.eu/reachit\\_en.asp](http://echa.europa.eu/reachit_en.asp)

ECHA holds its first stakeholder's day on October 10, 2008. The program is published here:

 [http://echa.europa.eu/home\\_en.asp](http://echa.europa.eu/home_en.asp)

The program is published here:

 [http://echa.europa.eu/doc/press/events/20081010\\_agenda\\_stakeholderday\\_20080723.pdf](http://echa.europa.eu/doc/press/events/20081010_agenda_stakeholderday_20080723.pdf)

General information and more events by ECHA, related to REACH, see the website:

 [http://echa.europa.eu/home\\_en.asp](http://echa.europa.eu/home_en.asp)

### Fees

Geert Dancet, executive director of the ECHA, has appealed to the European Parliament for additional subsidies for 2009; he had supplied in August the revenues forecasts. Three months, by September 1, before the deadline, pre-registrations had exceeded by far 200.000 ( total initially expected number) submitted by 7500 companies .Numbers had soared because of bulk registration of 500 substances had been made possible since July 22. There are fears that a substantial proportion of the preregistrations, for which companies pay no fee, will not convert into revenue-generating registrations ( expected to cover about 70 percent of ECHA revenues).

### Staff

Since its creation , ECHA has build up its staff level to more than 200 to reach 250 by end of 2008, 350 by 2009, 450 by 2010. (Source: ICS Chemical Business Sept.22, p.37)

### STILL important: REACH registration is starting on June 1, 2008!

The table below gives an overview on REACH information requirements and timetable reg. chemicals regulation: (Source/acc. to ICIS, Nov. 4, 2007)

Volume (tons/year)	1-10	10-100	100-1000	>1000
Preregistrations	12-18 months after entry into force (June-Nov. 2008)			
Information required	Identity of manufacturer Contact person Substance identifier Tonnage band			
Registration				
Information Annex	VII	VIII	IX	X
Chemical Safety Report	No	Yes	Yes	Yes
Time after entry into force	2018	2018	2013	End 2010
Registration	3,5 years (= End 2010)			

### Important and helpful:

**Price Waterhouse Coopers** has conducted a global survey on REACH and it turned out that many companies are not yet aware of the consequences of the REACH legislative. The report "Global companies weigh risks and rewards of Europe's newest law on the safe use of chemicals" can be loaded down from the PWC-website (at no cost) here:

 [http://echa.europa.eu/doc/press/080228\\_PR\\_MSC\\_1-Final%20\\_5.pdf](http://echa.europa.eu/doc/press/080228_PR_MSC_1-Final%20_5.pdf)

The Advisory Committee of the German Toxicology Society has recently published a review paper on the role of alternative testing methods in the frame of REACH and the Cosmetics Directive.

 <http://www.springerlink.com/content/55815583r850223w/>

Nature published an editorial in regard to animal testing within REACH:

Nature 453, 563-564 (29 May 2008) | doi:10.1038/453563b; Published online 28 May 2008 Animal tests inescapable - The ambitious scope of Europe's chemicals legislation demands some innovative toxicology.

Read more here:

 <http://www.nature.com/nature/journal/v453/n7195/full/453563b.html#top>



[www.epaa.eu.com](http://www.epaa.eu.com)

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## I.1.2. European Partnership on Alternative Approaches to Animal Testing (EPAA)

For outcome of the recent Mirror Group meetings and the last workshops, see the epaa-website:

 <http://ec.europa.eu/enterprise/epaa/uc.htm>

EPAA-newsletter of September 2008 is published and can be read here:

 [http://ec.europa.eu/enterprise/epaa/epaa\\_newsletter\\_200809.pdf](http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200809.pdf)

## NEWS:

Progress report 2007 published, next for 2008 to appear soon.

 <http://www.indepaa.org/EPAA/Pages/download?docid=4987>

EPAA-events are listed under: <http://www.epaa.eu.com>

This year's annual meeting is scheduled for November 3, 2008 in Brussels. Featured topic in 2008 is "3 Rs - Research", the title being: "[Research into alternative approaches \(3Rs\) in regulatory testing: Are we on the right track?](#)". The 3Rs Declaration can be found here:

 <http://ec.europa.eu/enterprise/epaa/3rd.htm>

The Mirror Group of stakeholders including the EP, animal welfare organizations (until recently), institutions and patient groups *ecopa* is represented by four of it's members. Next meeting of the Mirror Group will most likely be in spring of 2009.



<http://imi.europa.eu>

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### I.1.3. IMI is launched

The Innovative Medicines Initiative (IMI) has been launched on April 30, 2008. This is an initiative launched by both the European Commission and the EFPIA, the European Federation of Pharmaceutical Industry Associations. The goal of this initiative is to give an impulse to biopharmaceutical innovation in Europe. Universities, hospitals and public institutions can get financing for a research project.

IMI organises annual calls to be participated by academia and small companies. The subjects are determined by the EFPIA in cooperation with the European Commission. The first calls are out by now.

More information can be found here:

 [http://imi.europa.eu/docs/imi-scientific-priorities2008\\_en.pdf](http://imi.europa.eu/docs/imi-scientific-priorities2008_en.pdf)

 [http://imi.europa.eu/calls-01\\_en.html](http://imi.europa.eu/calls-01_en.html)

In July, a press release on the next steps was published, title being "The Innovative Medicines Initiative (IMI) continues into the next Phase"; full text under the below link:

 [http://www.imi.europa.eu/docs/press-release-17072008\\_en.pdf](http://www.imi.europa.eu/docs/press-release-17072008_en.pdf)

## I.2. Other News

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### I.2.1. Nanotech

The US Environmental Protection Agency (EPA) and its Science Policy Council has issued a nanotechnology white paper. The paper is aimed at providing information on the science issues and needs associated with nanotechnology, and to communicate them to stakeholders and the public.

 <http://www.epa.gov/osa/nanotech.htm>

Chronology up to now: February 2008: Commission's Scientific Committee on Consumer Products (SCCP) published its opinion on "Safety of nanomaterials in cosmetic products".

See resp. paper here:

 [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_123.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf)

June 17, 2008: The Commission is expected to publish a regulatory review to establish whether new legislation on nanomaterials is needed.

Early 2008: Establishment of an observatory to carry out dynamic assessments of nanotechnology development, use and scientific market developments, providing an 'early warning' system for the EU

institutions and member states.

By July 2008: The European Food Safety Authority (EFSA) publishes its general opinion on the potential risks of the use of nanotechnologies in the food sector. After that, the opinion will be submitted for public consultation.

### I.2.2. Review of Directive 86/609

A new draft was expected by June, latest by September 2008. There are indications that a new version has been drafted.

Progress can be followed under:



[http://ec.europa.eu/environment/chemicals/lab\\_animals/nextsteps\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/nextsteps_en.htm)



## II.1. EU 6th Framework Programme Projects / *ecopa* Working Groups

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### II.1.1.1. Recent News on FP6 and FP7 projects

#### NEWS:

Next Board Meetings scheduled (addressing also the START-UP project):

- February 25, 2009
- October 1, 2009

Representatives of *ecopa* in EU projects 6th Framework Programme:

- *SSA project ForInViTox* (Forum for researchers and regulators to meet manufacturers of toxicology test methods) - *ecopa* is represented by Dr. Odile De Silva.
- *BioSim* - Flavia Zucco represents *ecopa* in this EU Project.
- *CarcinoGENOMICS* - Bernward Garthoff is the *ecopa* representative in this IP FP6 project. *ecopa* has taken over the Work Package of dissemination of results of the consortium. [A questionnaire of the WP 11 regulatory group](#) can be found on the *carcinoGENOMICS* website for consultation and input. Input is requested and welcome from representatives of regulators, authorities, agencies and especially from toxicologists in industry and academia.
- *ACute Tox* - Peter Maier is the representative in the Advisory Board.
- *Sens-it-iv* - Vera Rogiers (represented by the *ecopa* secretariate) is the representative in the Advisory Board, and *ecopa* is seconding in the dissemination of results.
- *PREDICTOMICS* - Bernward Garthoff was the representative in the Advisory Board, the project has been finalized.
- *Liintop* - Horst Spielmann is the representative in the Advisory Board.
- *ReProTect* - Karin Gabrielson, Vera Rogiers and Bernward Garthoff (Chair) are representatives on the Supervising Board, and *ecopa* is seconding in the dissemination of results.
- *START-UP* - [START-UP](#) is the *ecopa*-follow-up-project for CONAM.
- *ESNATS* - *ecopa* is lead part of the dissemination workpackage.
- *ecopa* - latest *ecopa*-Board meeting took place on September 25, 2008 in Stockholm. The minutes of the Stockholm *ecopa* Board Meeting you can get here with the next messenger.

The European Commission has published a booklet on all European FP6-projects concerned with alternative testing.

You can download it from this link:



[http://www.ecopa.eu/download.php?file=alternative-test-strat\\_en.pdf](http://www.ecopa.eu/download.php?file=alternative-test-strat_en.pdf)

### II.1.1.2. Platforms

#### II.1.1.2.1. Austrian Platform

» [z e t - Austrian Centre for Alternative and Complementary Methods to Animal Testing](#)

- The 15th Linz-congress has taken place on September 19-21, 2008.
- Outcome:



<http://www.zet.or.at/node,3.de.kongress.php>

#### II.1.1.2.2. Belgian Platform

» [Foundation Prince Laurent](#)

### **II.1.1.2.3. Czech Platform**

» [CZECOPA](#)

### **II.1.1.2.4. Danish Platform**

» DACOPA

### **II.1.1.2.5. Dutch Platform**

» [NCA - The Netherlands Centre Alternatives to Animal User](#)

 [PDF: Latest issue of the NCA newsletter, published on May 24, 2008](#)

### **II.1.1.2.6. Finnish Platform**

» [Fincopa](#)

- Fincopa will organize in connection with the annual meeting in 2008 a seminar. In this seminar, state of the development of alternative methods will be presented. The follow-up of the alternatives applied in REACH will be another important topic.

### **II.1.1.2.7. French Platform**

- The French Platform was mentioned in the "European Biotechnology Journal" (no 5-6, volume 7, 2008) with an article. The title of the article is "Alliance to decrease animal tests". It mentions that the platform is raised by the French research ministry and the country's national medicines regulator (Afssaps). It also mentions that the French Platform is part of the *ecopa*-umbrella.

### **II.1.1.2.8. German Platform**

» [Stiftung set](#)

- The Annual Report for 2007 has been approved by the council on June 13, 2007 and is to be found on the website of set soon. The German version will be up first, it can be found on the first page, under 'Downloads', click on 'Tätigkeitsbericht 2007'. The English version will be online a few days later.

 <http://www.tierversuche-ersatz.de/>

 [PDF: set Activity Report \(76 kb\)](#)

### **II.1.1.2.9. Hungarian Platform**

- The new executive Board has been elected:  
It consists of Lajos Balogh, chair, Eva Hercsuth, heading the Animal welfare platform, Prof Tibor Bartha, heading the Academy, Laszlo Pallos, Authority Zsuzsa Somfai, Industry.

In context with the forthcoming START-UP event in Budapest in October 2009 addressing Replacement, jointly organized by the Hungarian and the German Platform, there will be a local Hucopa-event taking place as well.

### **II.1.1.2.10. Italian Platform**

» [IPAM - Italian Platform on Alternative Methods](#)

-  [PDF: IPAM annual report 2006 \(5 kb\)](#)

### **II.1.1.2.11. Irish Platform**

### **II.1.1.2.12. Norwegian Platform**

» [norecopa](#)

- Norecopa, Norway's National Platform for Alternatives to Animal Research, has its first birthday on 10th October. Norecopa is a member organisation with a board of 4 people representing the stakeholders, with personal deputies. So far, 30 of Norway's largest research institutions have become members.

Norecopa launched its own website in February ([www.norecopa.no](http://www.norecopa.no)) and has started a newsletter

which is sent out about every 4 weeks.

In May Norecopa arranged an international consensus meeting entitled "Harmonisation of the Care and Use of Animals in Field Research". This was the second consensus meeting of its kind: the first one was held in 2005 by the temporary platform before Norecopa was established and addressed fish as research animals. All the lectures from these meetings are on Norecopa's website or the website of the temporary platform (<http://oslovet.veths.no/fag.aspx?fag=56>). Following the meeting in May, the participants (a total of 50 people from all stakeholder groups in 5 countries) issued a consensus document summarising their views on the scientific and ethical challenges of wildlife research, including suggestions for Norecopa's work in this area. The document is available on Norecopa's website.

Since March, Norecopa has been in dialogue with the Norwegian Research Council to improve animal welfare in the area of fish research. In September the Council allocated NOK 200,000 (approx. 24,000 euros) to Norecopa to identify the need for more research within this area. A working group will be established to produce a report by June 2009. This will give the Council more information on how to prioritise research applications from fish researchers in the future.

Norecopa has also started cooperation with the Norwegian Animal Research Authority to produce guidelines for animal research. At present Norecopa is assessing the use of toe-clipping as a method for the identification and genotyping of neonatal transgenic mice.

Norecopa's annual budget is at present NOK 800,000 (approx. 96,000 euros). This is sufficient to finance the secretary in a part-time position (50%), the administrative work and some scientific activity. Norecopa is attempting to increase governmental funding, and not least, to persuade the government to establish a national fund for R&D work within the 3Rs.

Norecopa has compiled an Activity Plan for the next 3 years. Among these activities, Norecopa has organized a seminar on the use of statistical methods to reduce animal numbers, in connection with its AGM in June 2008. In autumn, Norecopa hopes to arrange the 3rd International Consensus Meeting, this time with fish as the central theme.

#### **II.1.1.2.13. Polish Platform**

» [polcopa](#)

#### **II.1.1.2.14. Spanish Platform**

» [REMA – Red Española para el Desarrollo de Métodos Alternativos a la Experimentación Animal](#)

- REMA has organized a meeting in parallel with the START-UP-expert meeting in Madrid in May. This meeting took place in the building of the Ministry of Health.
- The REMA activities can be found can at (Spanish version):

 <http://www.remanet.net/actividades/>

#### **II.1.1.2.15. Swedish Platform**

» [Stiftelsen Forskning utan djurförsök](#)

 <http://www.swecopa.se>

- **Government support for 3Rs research**

The Swedish government has promised an increase in funding for 3Rs alternatives: 13 million SEK in 2009 instead of the 8 millions that was allocated in 2008. This is still far from the 18,5 millions that was allocated in 2006, but a step in the right direction compared to the decreases faced in the last 2 years.

- News from Swecopa is published on the website [www.swecopa.se](http://www.swecopa.se) under "News". A newsletter in Swedish is also available at [http://www.swecopa.se/swe\\_sid5\\_aktuellt.html](http://www.swecopa.se/swe_sid5_aktuellt.html)  
E-mail us at [info@swecopa.se](mailto:info@swecopa.se) if you want to receive the newsletter.

#### **II.1.1.2.16. Swiss Platform**

» [3R Research Foundation Switzerland](#)

- Update on Activities:

September 8, 2008: Two new projects initiated by the 3R Research Foundation Switzerland.

Evaluation of lipid fractions for the substitution of serum in cell culture media Prof. Paul Honegger and Dr. Marie-Gabrielle Zurich, Department of Physiology, University of Lausanne, Switzerland.

 [http://www.forschung3r.ch/en/projects/pr\\_109\\_08.html](http://www.forschung3r.ch/en/projects/pr_109_08.html)

Development of an in-vitro assay for the screening of antischistosomal drugs Prof. Jennifer Keiser,

Swiss Tropical Institute, University of Basle, Switzerland.

 [http://www.forschung3r.ch/en/projects/pr\\_110\\_08.html](http://www.forschung3r.ch/en/projects/pr_110_08.html)

Latest bulletin of June 2008 "Bioconcentration of chemicals in fish can be assessed *in vitro*" to be found here:

 <http://www.forschung3r.ch/en/publications/bu37.html>

### Call for Grant Applications

The 3R Research Foundation invites interested scientists to propose a project which falls within the [principal areas for financial support](#). Information concerning current areas can be found in [3R-Info-Bulletin no.6](#). The duration of the project proposed should preferably be between 1 and 3 years and the necessary budget should be Sfr. 50 000.00 - Sfr. 300 000.00.

Successful projects will be selected according to the Foundation's [assessment criteria](#) as well as financial capacity.

The Foundation would like to point out that in the year 2008 about Sfr. 500 000.00 (310 000.00 EURO) are available for research grants.

Use the [application form](#) (by e-mail) and set up the proposal according to the [application format](#).

Deadline was September 1, 2008

Approach the [Scientific Adviser](#) for more information and material:

 [http://www.forschung3r.ch/en/information/adressen.html#wiss\\_mitarbeiter](http://www.forschung3r.ch/en/information/adressen.html#wiss_mitarbeiter)

Further details on the website:

 <http://www.forschung3r.ch/en/guidelines/index.html>

### Interested to form a new national platform in your country?

Please contact us (» [contact section](#)).

For an upfront info how to create a platform in your country, and which criteria to apply? See also the presentation of Jose Castell at the Stakeholder Workshop in Prague ECVAM/*ecopa* Stakeholder Workshop:

 [PDF: A guided tour to become full members/associate members in \*ecopa\* \(200 kb\)](#)

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**All the abstracts of the following projects are to be found on the forum of the *ecopa* website, see the comment under II.1.**



[www.reprotect.eu](http://www.reprotect.eu)

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#### II.1.2. ReProTect

This 6th FP-project, that *ecopa* had co-initiated and in which *ecopa* is represented with 3 members in the Supervising Board including the Chairperson, was started in 2003 with 21 partners.

The overall funding is scheduled to be 9.1 mio EUR, resp. 13.5 mio EUR. Contract with the EU was signed on July 1, 2004; the administration is performed by Prof. Michael Schwarz, University of Tübingen.

##### II.1.2.1. Recent News

The recent Supervising Board Meeting was held on July 8, 2008 in Dresden, Germany.

The Annual Research Area meeting and the Meeting of the Executive Committee was held in Stockholm, Sweden. A brochure on the ongoing activities within ReProTect is available.

 [PDF: ReProTect Brochure](#)

 [PDF: Executive Summary \(224 kb\)](#)

Also, please find a respective flyer below, and the brochure with first results.

 [PDF: ReProTect Flyer \(320 kb\)](#)



ecopa is involved in the Board and the results dissemination.



[www.acutetox.org](http://www.acutetox.org)

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### II.1.3. ACute Tox

#### II.1.3.1. Recent News

A list of all publications produced by the Consortium is available on the web site as well as the project structure and a profound overview. Link below.

The latest newsletter as of February 2008 can be read here:

 [http://www.acutetox.org/docs/Newsletter/acutetox\\_newsletter\\_3.pdf](http://www.acutetox.org/docs/Newsletter/acutetox_newsletter_3.pdf)

 <http://www.acutetox.org>

#### E-learning program for *in vitro* methods

The scientific coordinator of the FP6 project ACuteTox, Expertrådet, is producing an e-learning program for the testing strategy and the methods that will be the result of the project. To get a good implementation and a wide use of the *in vitro* methods it is important to make it convenient for the industry to use them. One way is to produce interactive manuals that make it possible to attain reproducible results with high and equal quality in all laboratories.

Expertrådet has developed a pedagogic model for an interactive manual within the ACuteTox project. The SOP text is supplemented with short video sequences, photos and drawings that clarifies critical phases of the test methods. Each test will be presented in three different levels: 1) an introduction level where the tests are presented briefly to demonstrate the opportunities of the test; 2) a second level with the SOPs of the tests and with video sequences or pictures that demonstrate how to carry through the tests; 3) in the third level the scientific documentation and background of the tests could be found. The second level is the main part of the e-learning program that will consist of the interactive manual.

This model could also be useful for the other FP6 projects within the *in vitro* area and it would certainly be convenient for the endusers if the e-learning programs from the different projects looked similar and had the same pedagogic model. Expertrådet is willing to assist other *in vitro* projects to produce similar e-learning programs.

Contact for more information: [www.expertradet.se](http://www.expertradet.se), [www.acutetox.org](http://www.acutetox.org)

 [http://www.ecopa.eu/download.php?file=ACuteTox\\_e-learning\\_abstract.pdf](http://www.ecopa.eu/download.php?file=ACuteTox_e-learning_abstract.pdf)

#### Consortium meeting held on February, 20-22, 2008 in Konstanz

After the consortium meeting held in February 2008 in Konstanz, the phase of data compilation and generation has been completed. At this meeting, new software (Acusoft) was presented which will facilitate the estimation and comparison of IC50 values from atypical dose-response curves obtained in different test systems and with different compounds. Furthermore the incorporation of chemical properties of a given compound (pH, lipophilicity, protein binding) was shown to be a good indicator of their kinetic behaviour and to be a very efficient corrector factor for the correlation between *in vivo* and *in vitro* data.

A new committee within the project was established from members of the advisory board and from ECVAM. Their task is to develop a test strategy, using the best performing assays in the testing of the 57 reference chemicals. This pre-validation phase will start in the second half 2008.



[www.sens-it-iv.eu](http://www.sens-it-iv.eu)

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#### II.1.4. Sens-it-iv

Sens-it-iv is an Integrated Project financially supported by a grant from the European Commission (LSHB-CT-2005-018681). 28 groups overall, of which 9 represent industry. 15 groups represent universities or research institutes, while 4 groups represent organizations.

##### II.1.4.1. Recent News

*ecopa* is part of work package 9 and is responsible for "Technology transfer and Dissemination". Technology transfer and dissemination of project results, including knowledge, will be a key activity throughout the term of the Sens-it-iv project.

*ecopa* has taken over the responsibility "spreading the news/results" of this EU project, and released a brochure covering the activities on behalf of Sens-it-iv, and supported the website creation. The folder and poster can be downloaded on the website [www.sens-it-iv.eu](http://www.sens-it-iv.eu), section press material. Technology transfer and dissemination of project results, including knowledge, will be a key activity throughout the term of the Sens-it-iv project.

The first Sens-it-iv Newsletter appeared on December 14, 2006 and now the 21st edition is available via the website or the link below. *ecopa* is part of work package 9 and is responsible for "Technology transfer and Dissemination". The newsletter is coordinated by the WP9 leader.

Newsletter Nr. 21 is out:

 <http://www.sens-it-iv.eu/content/newsletter.php>

Newsletter-subscription possibility on the website.

The yearly organised General Assembly will take place from October 21-23, 2008, in Maribo, Denmark.

 [PDF: Sens-it-iv - First publishable summary \(114 kb\)](#)

 [PDF: Sens-it-iv - Publishable executive summary - 2nd year \(80 kb\)](#)



<http://www.biosim-network.net>

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#### II.1.5. BioSim

BioSim, or "Biosimulation A New Tool in Drug Development" started December 1, 2004. BioSim is a Network of Excellence supported by the European Commission as part of its 6th Framework Programme.

##### II.1.5.1. Recent News

Report by Flavia Zucco, BioSim Advisory Scientific Board:

The 4th BioSim Conference was held in Budapest from September 24 to 27, 2008. The advancements of this NoE are impressive and strong networking collaborations have been by now established. It is worthwhile to mention the books published, which make this network the leader in Europe in opening the way to integrated research in the interdisciplinary area of biological system simulations.

Martin Bertau, Erik Mosekilde and Hans Westerhoff have edited a book for Wiley-VCH on '*Biosimulation in Drug Development*' with contributions from a significant number of BioSim-partners. With its 512 pages and 18 chapters, the book provides what can be considered the first comprehensive presentation of some of the most important aspects of modeling and simulation in drug development and health care.

Fred Boogerd, Frank Bruggeman, Jan-Hendrik Hofmeyr, and Hans Westerhoff (partner 3) have published a book entitled: '*Systems Biology: Philosophical Foundations*' that touches on the problem of whether Biology is entitled to its own scientific foundation rather than being subjected to existing frameworks.

Olga Sosnovtseva and Erik Mosekilde (partner 1) have edited a special issue of Journal of Biological Physics on '*Biosimulation*' with a significant number of BioSim-contributions, and Morten Brøns (also partner 1) is co-editor of a special issue of the *American Physical Society Journal Chaos* on '*Multi-mode Dynamics*'.

One of the most important aspects of that project is that it has been trying to cover the wide approach to the different levels of complexity of the living organism: it has always tried to couple the micro to the macro levels, from the molecular to the physiological and clinical ones. However the main problem is now how to go on, since it is going to the end by November 2009 and no NoE calls are available in the

7FP. The hope is that the partners which have been the core of BioSim will be able to sort out an IP of about 15 participants, taking on the most promising lines of research produced by BioSim. The next final Conference is scheduled for the end of August 2009 in Copenhagen, the town of the Coordinator Prof Erik Mosekilde.

 <http://www.biosim-network.net>

## **Liintop**

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### **II.1.6. Liintop**

#### **II.1.6.1. Recent News**

Structure of the project, information on partner and new on events can be taken from the website:

 <http://www.liintop.cnr.it/index.php?PG=events&action=events>



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### **II.1.7. carcinoGENOMICS**

carcinoGENOMICS is an Integrated FP6 Project financially supported by the European Commission (LSHB-CT-2006-037712). 19 groups are present of which 6 represent industry, 11 represent universities or research institutes, while 2 groups represent organizations.

#### **II.1.7.1. Recent News**

 [PDF: CarcinoGENOMICS Press Release \(24 kb\)](#)

The last carcinoGENOMICS-Project Board was held on September 15/16, 2008 in Brussels, Belgium. The next carcinoGENOMICS Annual Meeting will be held on November 10-12, 2008 in Dublin, Ireland.

A workshop on Regulatory Aspects with experts of that scene was held on June 9 and 10, 2008, in Brussels, Belgium, in the premises of the EU Commission.

 <http://www.carcinogenomics.eu/index.php?id=110>

## **II. 2. EU 7th Framework Programme Projects, Initiatives and Technology Platforms**

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**SusChem**

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### **II.2.1. Sustainable Chemistry (SusChem)**

The Technology Platform SusChem has been formed and finalized its Implementation Action Plan. The action plan can be downloaded from the SusChem website.

 <http://www.suschem.org/>

The tenth SusChem newsletter is now online:

 <http://www.suschem.org/content.php?pageId=3653>

A detailed review of the SusChem platform activities can be found in a supplement of the September 22 issue of the ICIS Chemical Business.

### **II.2.2. Regulations of the 7th Framework Programme**

Update 7th EU RTD- Framework Programme

Though intended as part of the EU-competitive efforts in Research and Development, the EU still is behind its own targets laid down in the Lisbon Strategy. According to the EU statistics officer, the 27 EU states invested in 2006 as much (or little) as in the year before, i.e. 210 billion EURO equivalent to 1.84% of its economical output. Lisbon asks for 3% in 2010.

### Guidance on FP7 implementation

A number of guidance documents and preparatory work are carried out by the European Commission in view to install the basis of the FP7 implementation. The following documents are available for consultation on [http://cordis.europa.eu/fp7/find-doc\\_en.html](http://cordis.europa.eu/fp7/find-doc_en.html) where they can also be downloaded:

- a standard Model Grant Agreement,
- a draft Guide for Beneficiaries,
- a draft Guide to Financial Issues,
- a draft Guide to IPR and
- a draft Checklist for the Consortium Agreement.

*ecopa* is interested to participate with partners in some of the calls dealing with alternative methods and being announced in the future, esp within the HEALTH resp. the ENVIRONMENT sectors of the 7th FRP.



START-UP

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### II.2.3. START-UP

*ecopa* submitted a proposal for a Support Action in the HEALTH-2007-1.3-2 call: Bottlenecks in reduction, refinement and replacement of animal testing in pharmaceutical discovery and development. The proposal is called "**Scientific and technological issues in 3Rs alternatives research in the process of drug development and Union politics**" with the acronym: **START-UP**. Several NCPs are collaborating in this project. The project was approved "Grant Agreement" No. 201187 and signed on March, 12, 2008.

#### II.2.3.1. The Abstract of the proposal

The **START-UP** project is concerned with the identification and proposals to abolish bottlenecks in the 3Rs approach in pharmaceutical discovery and development. The goal of the project is the organisation of 3 **Workshops** in order to determine a) the state of the art of each of the 3Rs in the EU, b) to assess European strength and gaps in 3Rs and c) the identification of rate limiting steps on the political, scientific, technological level. As a result, a Consensus Paper containing the concepts and suggestions for a Roadmap for future research will be produced.

Stakeholders (among them European Pharmaceutical Industries (EPI)) have identified bottlenecks in drug development and in the integration of *in vitro* methods. Early identification of wrong candidates for further development and avoiding efforts for under-performing candidates, are essential for the competitiveness of European Industry. Identification of bottlenecks in the implementation of reduction, refinement and replacement of animal experimentation in drug R&D, should assist in identifying the best *in vitro* and *in vivo* systems, and to speed up the drug development process. Existing hurdles in the scientific, technological, political and environmental level (including regulatory), play a substantial role and are rate-limiting in developing new drugs, including biological entities (almost 50% of the currently developed products).

*ecopa* (the quadripartite umbrella NGO for alternatives) structures with its VUB partner this support action around 3 major workshops which will be preceded by 3 Expert Meetings redefining and prioritising current bottlenecks in 3Rs methodology; with EPI, drug discovery and development. Each phase has its own specific needs, and analysing the present limitations and gaps needs to be addressed, e.g., many cell systems do not yet have the required stability for genomics, proteomics or metabonomics analysis; many current *in vitro* cell systems lack crucial bioactivation capability. Consequently, the status of satisfactory "predictive" pharmacology and toxicology *in vitro* has not yet been reached.

In terms of politics and ethical concerns, considerable differences in regard to the use and development of transgenic animals, human tissues and stem cells create an atmosphere of insecurity for an effective academia and industry cooperation.

The final goal of this action is a Consensus Document that analyses present status.

Details of the project were presented by the Chair of *ecopa* on the occasion of the 11th Linz Alternative Congress, September 28-30, 2007.



**NEWS:** The first START-UP expert meeting has taken place in Madrid, on June 19, 2008. On June 20, 2008, there was a public meeting, organized by REMA together with *ecopa*. The second expert meeting has taken place in Basle, Switzerland, on the Novartis Campus, with participation of industry representatives on September 5, 2008. The third expert meeting is organized together with the eSI workshop. This currently takes place in Pueblo Acantilado/ Spain from October 16 to 19, 2008.

The first major workshop of the START-UP project , on Refinement, will be held in Rome, at the L'Istituto Superiore di Sanità (ISS) on February 26-27, 2009, starting at 14:00 on Thursday and ending at 13:00 on the next day Friday.



ESNATS

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#### II.2.4. ESNATS

Project acronym: ESNATS

Project full title: Embryonic Stem cell-based Novel Alternative Testing Strategies

Grant agreement no.: FP7 - 201619.

The aim of the ESNATS project is to develop a novel "all-in-one" toxicity test platform based on embryonic stem cells (ESCs), in particular human ESCs, to accelerate drug development, reduce R&D costs and propose a powerful alternative to animal tests in the spirit of the "Three R principle". ESNATS objectives will be achieved in a 5 year multi-disciplinary collaboration of leading European researchers in alternative testing, toxicology, ESC research, genomics, modelling, and automation. The consortium will also include representatives from regulatory bodies, the pharmaceutical industry and ethical advisors to provide guidance to ensure rapid applicability of the developed test systems.

*ecopa* has taken over some tasks in disseminating results of this project, developed the logo, and is leading the respective workpackage.

#### **NEWS:**

ESNATS Kick-Off meeting was held from April 21 to 23 in Cologone, Germany. Dr. Bernward Garthoff presented *ecopa* and the work which *ecopa* will do in the Workpackage 5 of ESNATS. The next Board meeting will be held end of October in Dortmund.

The above ESNATS logo was brought in by *ecopa*.



#### Miscellaneous

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#### III.1. Events

##### III.1.1. *ecopa* events

##### III.1.1.1. 9th Annual *ecopa* Workshop

The next, 9th Annual *ecopa* Workshop will take place on November 29-30, 2008 in Brussels.

The future *ecopa* Annual Meetings will be:

10th: November 28-29, 2009

11th: end of November 2010

##### III.1.1.2. *ecopa* Board meeting



[Minutes \*ecopa\* Board Meeting of March 4, 2008 \(180 kb\)](#)

The next *ecopa* Board meetings (addressing also the START-UP project):

- February 25, 2009 in Rome, Italy

- October 1, 2009 in Budapest, Hungary



*ecopa*  
Science  
Initiative

eSI - *ecopa* Science Initiative

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### III.1.1.3. eSI: *ecopa* Science initiative

The eSI-Conference under the general heading: "Reaching the young scientist" is an initiative organised by *ecopa* aimed at bringing together senior as well as young researchers to discuss about the new technologies and their applicability in 'in vitro' research as well as to improve creativity and innovation in the search for alternative methods. *ecopa* had performed a detailed literature analysis of the last 5 years of research in alternative methods and had concluded that this area of applied research is drying out.

The full report, presentations, and the final program are listed [on the \*ecopa\* website in the archive section](#).

**NEWS:** The recent workshop currently takes place in Pueblo Acantilado; Alicante, Spain on October 16-19, 2008, with the attendance of senior scientists and young researchers of 14 countries. It focusses on "Recent developments and potentially novel approaches of science to alternative testing of cosmetics and pharmaceuticals". It is being held together with the European Partnership for Alternative Approaches to Animal Testing, EPAA.

Find the programme of the eSI-workshop here:

 [http://www.ecopa.eu/doc/WebESI\\_2008/indexESI.htm](http://www.ecopa.eu/doc/WebESI_2008/indexESI.htm)

New aspects of pharmaceutical and cosmetic research are covered also in regard to the START-UP project. Sponsoring is provided by Badicos/Rogiers, Bayer, set and EPAA.

### III.1.2. other events

#### III.1.2.1. Discovery on Target

Cambridge Healthtech Institute's Sixth Annual, October 20-23, 2008, World Trade Center

For more information visit:

» <http://www.healthtech.com/DOT/overview.aspx?&c=494>

#### III.1.2.2. HESI Toxicogenomics Committee Workshop

Genomics Applications in Safety Studies - Case Study Workshop. Organized by the HESI Committee on Application of Genomics in Risk Assessment, October 27-28, 2008 Arlington, Virginia, Palomar Hotel. For more information visit:

#### III.1.2.3. INVITROTRAIN: Practical Training Courses on Alternative Test Methods

Objectives of the INVITROTRAIN project:

The objectives of the INVITROTRAIN project under the European Regional Development Fund are the development, validation and demonstration of *in vitro* methods for chemical testing and prediction of toxicity. Education and training is the primary component of this project which aims for the dissemination of alternative (non-animal) methods and the enhancement of the link between scientists in the *in vitro* field and technology users. The courses are organised by the Institute of Pharmacy at the Freie Universität Berlin in cooperation with the German Federal Institute for Risk Assessment (BfR). Topical toxicity, October 29-31, 2008, Institut für Pharmazie, Freie Universität Berlin, Germany.

For detailed information:

» <http://userpage.fu-berlin.de/~invitrot/>

#### III.1.2.4. EPAA - Annual Conference «Research into alternative approaches (3Rs) in regulatory testing: Are we on the right track?», Brussels, November 3, 2008

Announcement and call for posters:

» [http://ec.europa.eu/enterprise/epaa/conf\\_2008\\_second\\_announcement.pdf](http://ec.europa.eu/enterprise/epaa/conf_2008_second_announcement.pdf)

Registration form:

» [http://ec.europa.eu/enterprise/epaa/reqform11\\_2008.htm](http://ec.europa.eu/enterprise/epaa/reqform11_2008.htm)

European Commission, DG Research / DG Enterprise and Industry, Brussels

#### III.1.2.5. Final Symposium on RNA Interference for therapeutic approaches

organised by the RIGHT Consortium, the Symposium is taking place in Brussels on November 3-5, 2008.

For more information:

» <http://www.rightsymposium2008.eu>

### **III.1.2.6. Biomarkers Europe**

November 10-11, 2008, Intercontinental Wien, Vienna, Austria

For more information:

» <http://www.biomarkerseurope.com>

### **III.1.2.7. TestSmart DNT-2 Developmental Neurotoxicity, November 12-14, 2008, Reston, Virginia USA**

Creating a humane and efficient approach to developmental neurotoxicity testing. This meeting will assess progress made in developing DNT alternatives, reassess the priorities and recommendations established at DNT-1 and establish ways to use *in vitro* data in decision making.

For more information:

» <http://caat.ihsph.edu/dnt2>

### **III.1.2.8. FP7 - Financial & Project Management**

November 13-14, 2008, Budapest, Hungary

For more information:

» [http://www.eustrainingsite.com/open\\_details.php?id=45](http://www.eustrainingsite.com/open_details.php?id=45)

### **III.1.2.9. Integrated Testing Strategies for REACH - 2nd Workshop**

Practical answers to your questions.

November 17, 2008, at the Club of University Foundation in Brussels, Belgium.

For more information:

» <http://www.osiris-reach.eu/>

### **III.1.2.10. In Vitro Toxicology Society: Winter meeting: registration and call for abstracts - Winter Meeting Programme**

Main Theme: Safety Pharmacology. Posters/oral communications open to all areas of in vitro toxicology. Wellcome Collection Conference Centre, Euston, London, November 19, 2008

Details of the venue can be found at:

» <http://www.wellcomecollectionconference.org/>

### **III.1.2.11. LRI 10th Anniversary Event : Innovative science for environment and health: Tools for REACH and beyond**

November 20-21, 2008, Hotel Amigo, Brussels, Belgium

Goals of the workshop: Highlight research topics LRI has addressed in the past, as well as identify critical issues for future environment & health research. LRI will draw on the expertise of distinguished attendees from academia and government.

Further details, workshop programme and registration:

» <http://www.cefic-lri.org>

### **III.1.2.12. 21st Century Medicine: Breakthroughs and Challenges**

Some of the most exciting research in the world is being undertaken in the field of medicine. Many challenges exist in identifying disease at the earliest possible stage and preventing and treating cancer, congenital, degenerative and infectious diseases – and increasingly, lifestyle induced diseases such as diabetes. Even greater challenges exist in bringing affordable, safe medicines to a wide population, and in enabling the elderly to remain active and maintain their faculties for as long as possible.

International experts on greatest medical challenges, on using the new technologies to unravel the secrets of illness and creation of means to live longer, healthier lives. November 26-27, 2008, The Royal Institute of British Architects, London.

More information and program:

» <http://www.nano.org.uk/conferences/nanomed2008/proq.htm>

### **III.1.2.13. New Horizons in Toxicity Prediction**

Symposium in collaboration with the University of Cambridge, December 8-9, 2008, hosted by The University of Cambridge, Cambridge, UK

Detailed information and registration:

» <http://www.lhasasymposium.com/registration-contact.html>

### **III.1.2.14. Pharma Business Strategies for Biomarkers**

Are Biomarkers Required in the New Pharma Dealmaking World? December 11-12, 2008, InterContinental Mark Hopkins Hotel, San Francisco

For more information:

» <http://www.windhover.com/pbsb>

### **III.1.2.15. Benelux Bioinformatics Conference**

The Benelux Bioinformatics Conference (BBC) is a two-day international conference on bioinformatics. The BBC is the primary community event for bioinformatics researchers in the Netherlands, Belgium, and Luxemburg with excellent networking opportunities. The conference is aimed at both academic and industry researchers. December 15-16, 2008.

For more information:

» <http://www.nbic.nl/bbc2008/>

### **III.1.2.16. Mondial Research Group's 4th Annual International Conference on "Predictive Human Toxicity and ADME/TOX Studies"**

Predictive Human Toxicity and ADME/Tox Studies 2009 is scheduled for the January 22/23, 2009 in Brussels, Belgium. Two-day training course on ADME, PK/TK, and Drug Metabolism in Drug Discovery and Development preceding the conference. January 20/21, 2009.

For more information:

» <http://www.mondialresearchgroup.com/index.php?whereTo=humt09>

### **III.1.2.17. FIRST ANNOUNCEMENT for the 7th WORLD CONGRESS on Alternatives**

Rome / Italy , August 30 to September 3, 2009

For more information:

» [http://www.vet.uu.nl/viavet/viavet\\_english/departementen/dwm/3r\\_symposium](http://www.vet.uu.nl/viavet/viavet_english/departementen/dwm/3r_symposium)

## **III.2. Awards and Publications**

### **III.2.1. Cefic-LRI and EUROTOX 2008 Innovative Science Award**

The €100,000 prize, which aims to promote innovation in the field of toxicology, will be awarded this year by the LRI (Long Range Research Initiative) in conjunction with EUROTOX (Federation of European Toxicologists & European Societies of Toxicology).

The application deadline was March 03, 2008, competition is ongoing, time schedule here:

**June 26, 2008**

Finalists' project presentation to the selection committee in Brussels

**November 20-21, 2008**

Presentation by the award winner at the Cefic LRI annual Workshop, Brussels, Belgium

For more information and finalists/themes visit:

» <http://www.cefic-lri.org>

### **III.2.2. Dieter Lütticken Award**

#### **Intervet's award 2008: Deadline**

The Dieter Lütticken award, established in 2004, aims to encourage research into the use of alternative models for animal testing with significant impact on the development or production of new animal health products. Intervet/Schering-Plough Animal Health welcomes submissions from scientists and public life-science institutions. The € 20,000 award is named after Dr. Dieter Lütticken, a committed researcher in microbiology and virology. He guided and shaped Intervet's R&D for more than a quarter of a century. Dr. Lütticken retired in 2003 from his position as Vice President and Head of R&D. The award's scope covers *in vitro* models used in R&D which replace animal testing for licensing purposes as well as studies avoiding the use of animals in efficacy, safety and quality testing in the production of biologicals and pharmaceuticals for animals.

A jury panel composed of experts from public institutions of the animal health/animal testing sector and Intervet representatives looks for possible candidates and makes the final selection. Intervet also welcomes submissions from all life-science research institutions. Commercial organizations are excluded.

This year's deadline is November 15, 2008.

» <http://www.intervet.com>



### III.2.3. EPAA Newsletter and Annual Conference

The latest edition of the EPAA-newsletter (July 2008) is available now:

» [http://ec.europa.eu/enterprise/epaa/epaa\\_newsletter\\_200807.pdf](http://ec.europa.eu/enterprise/epaa/epaa_newsletter_200807.pdf)

Annual Conference: «[Research into alternative approaches \(3Rs\) in regulatory testing: Are we on the right track?](#)».

Brussels, November 3, 2008

Announcement and call for posters:

» [http://ec.europa.eu/enterprise/epaa/conf\\_2008\\_second\\_announcement.pdf](http://ec.europa.eu/enterprise/epaa/conf_2008_second_announcement.pdf)

Registration Form:

» [http://ec.europa.eu/enterprise/epaa/regform11\\_2008.htm](http://ec.europa.eu/enterprise/epaa/regform11_2008.htm)

European Commission, DG Research / DG Enterprise and Industry, Brussels

### III.2.4. InterNICHE: 2008 Humane Education Award

Interniche announces the 2008 Humane Education Award to support ethical and effective life science education and training.

The Award is a grant program to enhance biological science, medical and veterinary medical education and training. Supported by Proefdiervrij, the Award offers 20,000 Euro (US\$ 25,000) to be split between successful applicants.

Proposals are invited from all countries for initiatives to replace animal experiments and the dissection of purposely killed animals. Applicants may be teachers, students, campaigners or any other individuals committed to best practice education and training.

For more information see the website:

» <http://www.interniche.org>

### III.2.5. Nature: Editorial – Animal tests inescapable

Nature published an editorial in regard to animal testing within REACH:

*Nature* **453**, 563-564 (29 May 2008) | doi:10.1038/453563b; Published online 28 May 2008 Animal tests inescapable - **The ambitious scope of Europe's chemicals legislation demands some innovative toxicology.**

Read more here:

» <http://www.nature.com/nature/journal/v453/n7195/full/453563b.html#top>

### III.2.6. Booklet on Alternative Testing Strategies

The European Commission has published a booklet on all European FP6-projects concerned with alternative testing.

You can download it from this link:

» [http://www.carcinogenomics.eu/files/public/home/alternative-test-strat\\_en.pdf](http://www.carcinogenomics.eu/files/public/home/alternative-test-strat_en.pdf)

### III.2.7. CHI's Insight Pharma Report

**Systems Biology: A Disruptive Technology**": This report focuses on the current and future applications of Systems Biology in drug discovery, specifically in pinpointing optimal individual targets, and combinations of targets, to overcome metabolic pathway redundancies, leading to efficacious and safe products.

For more information:

» [http://www.chicorporate.com/Systems\\_Biology/br+dl.aspx](http://www.chicorporate.com/Systems_Biology/br+dl.aspx)

### III.2.8. Structure-Based Drug Design: Conference proceedings CD available

The conference proceedings of the CHI's Eighth Annual Structure-Based Drug Design conference, which took place in June in Boston, MA are available on CD. This CD features 25 speakers' slides and papers. It is available for \$250.

You can order it here: <http://www.healthtech.com/Conferences/CompactDiscs.aspx>

For more information:

» <http://www.chicorporate.com/>

### **III.2.9. The European Medicines Agency (EMA) has published a draft document for consultation**

'EMA/CHMP Working Group with Healthcare Professionals - Recommendations and Proposals for Action' (EMA/185036/2008).

The document is available here:

» <http://www.emea.europa.eu/pdfs/human/hcpwq/18503608en.pdf>

### **III.2.10. The European Medicines Agency (EMA) has published a concept paper on 'single dose/acute toxicity'**

The document is available here:

» <http://www.emea.europa.eu/pdfs/human/swp/30241308en.pdf>

### **III.2.11. AltTox Newsletter, September 2008**

The latest edition of the AltTox-newsletter (September 2008) is available now.

You can subscribe for this here:

» <https://community.hsus.org/alttox/join.tcl>

### **III.2.12. NC3Rs Newsletter 17, September 2008**

The 17th edition of the NC3Rs-newsletter (September 2008) is available now.

You can subscribe for this here:

» <http://www.nc3rs.org.uk/signup-newsletters.asp>

### **III.2.13. New Book out regarding "Safety Assessment of Cosmetics in Europe"**

For more information:

» [http://www.ecopa.eu/download.php?file=Book\\_Pauwels\\_Roijers\\_advert.pdf](http://www.ecopa.eu/download.php?file=Book_Pauwels_Roijers_advert.pdf)

## **III.3. Calls and Vacancies**

### **III.3.1. The ECLAM ESLAV Foundation is now accepting applications for funding in 2008-2009**

It is a charitable organization that funds studies for the discovery, validation and implementation of refinement of the care and use of animals in research. In particular the Foundation funds small studies, up to 20000 euros in the following areas:

- Refinement in experimental techniques, anaesthesia and analgesia to reduce pain and distress
- Objective measures of animal welfare.
- Studies to ensure scientific basis for housing and husbandry standards
- Validation of environmental enrichment to improve behavioral well being

Funding applications for 2007-2008 are closed. 2008-2009 applications are open (early 2008) for information only an application form, including guidelines for applicants and information how to submit an application, can be downloaded here: [2008 form](#).

The Foundation's website can be found at:

» <http://www.eclameslavfoundation.org>

with a grant application form at:

» <http://www.eclameslavfoundation.org/applications.htm>

A leaflet describing the Foundation is available at:

» <http://www.eclameslavfoundation.org/promotion/2007Flyer.pdf>

### **III.3.2. Call for expression of interest as Members of the Board of Appeal of ECHA**

The European Commission has published a call for expression of interest in the appointment as chairman and as members of the Board of Appeal of the European Chemicals Agency. For further information see the attached notice and the addresses (links) mentioned in the notice.

» [http://echa.europa.eu/doc/press/20080201\\_PR\\_08\\_01RAC.pdf](http://echa.europa.eu/doc/press/20080201_PR_08_01RAC.pdf)

### III.3.3. Call for interest for Grantholders for Doctoral and Post-doctoral positions in ECVAM

The Institute for Health and Consumer Protection (IHCP) has launched a call for interest for Grantholders for Doctoral, Post-doctoral and Senior Research Positions. ECVAM, part of the IHCP, offers two of the Grantholders positions.

For more information:

» [http://ihcp.irc.ec.europa.eu/job/Grantholders\\_open\\_calls.htm](http://ihcp.irc.ec.europa.eu/job/Grantholders_open_calls.htm)

### III.3.4. New call for Marie Curie Actions

A complete overview of relevant calls can be found at:

» <http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7SubmitProposalPage>

The Intra-European fellowship can be found at:

» [http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7DetailsCallPage&CALL\\_ID=118#infopack](http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7DetailsCallPage&CALL_ID=118#infopack)

### III.3.5. Third FP7-HEALTH call

The publication of the third call for the FP7-HEALTH program, with an indicated budget of 590 million euro, has been postponed. The call has been published in September, with the deadline of submitting before December 3, 2008.

The actual text for the most interesting part of a support and coordinating action, is given below. *Ecopa* is interested to support parties building consortia in response to this call. Please contact our secretariat to learn more about it.

Topic for 3rd call, single-stage submission and evaluation; **deadline 3 December 2008: - HEALTH-2009-1.3-1: New initiatives towards the implementation of the Replace, Reduce and Refine strategy. FP7-HEALTH-2009-single-stage.** The development of new '3R'-methods as modern alternative approaches to safety testing requires a better co-ordination of the various activities involved. This should start with the mapping of existing research results, followed by the development of new ideas for alternative approaches and strategies, and promotion of communication, education, validation and acceptance of alternative approaches. The funding scheme would be a support and co-ordination action aimed at bringing academic research in a pro-active way closer to the industrial landscape in order to effectively develop concrete collaboration projects with industrial partners. This coordination action should build particularly on the success of activities carried out in the EU RTD Framework Programmes and in national activities. **Funding scheme:** Coordination and Support Action (Coordinating Action).

The following specific CORDIS address leads you to the work programme of HEALTH (via "Information package"):

[http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7DetailsCallPage&call\\_id=140&act\\_code=HEALTH&ID\\_ACTIVITY=1](http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.FP7DetailsCallPage&call_id=140&act_code=HEALTH&ID_ACTIVITY=1)

The maximum EU contribution to Coordinating Actions is 1.5 million EURO. Duration: 3 - 5 years.

### INFO ABOUT THE FP7 HEALTH CALL3

It is to be expected that there will be two parallel calls with 2 deadlines.

One in which the *single-stage hand over/evaluation* will be applied (for most of the topics)

#### **FP7 Health-2009-single-stage (call A)**

for small-scale collaborative projects

indicative budget: 476 Million €;

deadline: November 20, 2008.

» [http://www.ecopa.eu/download.php?file=Call\\_FP7\\_03\\_09\\_2008\\_a\\_ct\\_200901\\_en.pdf](http://www.ecopa.eu/download.php?file=Call_FP7_03_09_2008_a_ct_200901_en.pdf)

A second one in which *two-stage hand over/evaluation* will take place (only for some topics)

#### **FP-Health-2009-two-stage (call B)**

indicative budget: 115 Million €.

deadline stage 1 of call B: October 21, 2008

deadline stage 2 of call B: February 19, 2009

» [http://ec.europa.eu/research/future/themes/index\\_en.cfm](http://ec.europa.eu/research/future/themes/index_en.cfm)

## III.4 VARIA

### III.4.1 Public Consultation on the Green Paper 'European Research Area: New Perspectives'

The European Commission invites citizens and stakeholders to participate in the debate on the European Research Area (ERA), in particular by putting forward their views in this public consultation. The consultation is based on the questions raised in the Green Paper 'The European Research Area: New Perspectives'.

The results of the debate will be used by the Commission to prepare initiatives that will be proposed in 2008.

More detailed information can be found on:

» [http://ec.europa.eu/research/era/consultation-era\\_en.html](http://ec.europa.eu/research/era/consultation-era_en.html)

For more information and to participate in the consultation please visit the consultation web site.

» <http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=ERAGreenPaper>

#### **III.4.2. The NC3Rs - Information Portal - Species selection**

The British NC3Rs has an extensive Information Portal where to find a wide range of references and links for guidance on implementing the 3Rs.

A new section on [species selection](#) has recently been added. Where animal use is necessary in research or testing, the choice of species (and breed/strain) should always be carefully considered and justified. This page sets out some of the factors to consider, particularly in relation to the 3Rs.

#### **III.4.3. NC3Rs announces new Board Chair as Professor Ian Kimber**

Professor Ian Kimber, University of Manchester, has been appointed as the new Chair of the Board of the NC3Rs.

Professor Kimber will lead the Board, which oversees policy and strategy and is consulted on major spending decisions, from 3 July 2008 for a three year term. He replaces Lord Turnberg of Cheadle, who led the Board from May 2004 till October 2007.

For more information:

» <http://www.nc3rs.org.uk>

#### **III.4.4. The DB-ALM has published a new data sector**

In addition to the new information on methods recently published, the DataBase on ALternative Methods (DB-ALM) of the Institute for Health and Consumer Protection (IHCP) to which ECVAM belongs to has also made available for public access the directory on contact details of: "Persons & Institutions active in the Field of Alternative Methods."

For more information:

» <http://ecvam-dbalm.jrc.ec.europa.eu>

#### **III.4.5. CARDAM: Centre for Advanced Research & Development of Alternative Methods**

CARDAM is a newly formed institute for research and development of alternative methods.

For more information:

» <http://www.cardam.eu/CARDAM>

#### **III.4.6. VirtualToxLab is available on the internet**

After 25 years of research, VirtualToxLab an *in silico* tool for predicting the toxic potential of drugs and environmental chemicals is accessible through the Internet. Its fully automated protocol allows to estimate the binding affinity of any molecule of interest towards a series of proteins, known or suspected to trigger adverse effects by simulating and quantifying their interactions with the human protein at the molecular level using automated, flexible docking combined with multi-dimensional QSAR. In contrast to other approaches in the field, this technology does not only provide a binding affinity but allows to verify the result at the molecular level by interactively viewing the corresponding protein-ligand complex in 3D. Currently, the *VirtualToxLab* includes 11 validated models for the androgen, aryl hydrocarbon, estrogen, glucocorticoid, mineralocorticoid, thyroid and peroxisome proliferator-activated receptor as well as for the enzymes CYP3A4 and CYP2A13. The VirtualToxLab is accessible from any hard and software platform.

Full details are given in the 2008 Newsletter which is available for download at:

» <http://www.biograf.ch/downloads/newsletter.pdf>

#### **III.4.7. Professor on "Alternatives to animal experiments in toxicological risk assessment" at Utrecht University**

Dr. Bas J. Blaauboer from the Institute for Risk Assessment Sciences, part of the Division of Toxicology at the University of Utrecht has been promoted to professor on " Alternatives to animal experiments in toxicological risk assessment". This was possible thanks to funding they got from a private society, which also enables them to work for six years with a group of 5 people on the implementation of alternatives in toxicology.

Website IRAS:

» <http://www.iras.uu.nl>

#### **III.4.8. The German Federal Institute for Risk Assessment (BfR) has job opportunities**

The Federal Institute for Risk Assessment (BfR) is the scientific body of the Federal Republic of Germany that prepares expert reports and opinions on issues related to food safety and consumer health protection.

For more information:

» <http://www.bfr.bund.de>